

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNITED THERAPEUTICS)	
CORPORATION and)	
SUPERNUS PHARMACEUTICALS, INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 21-489 (RGA)
v.)	
)	
ANI PHARMACEUTICALS, INC.,)	
)	
Defendant.)	

SCHEDULING ORDER

This 23rd day of June, 2021, the Court having waived an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED that:

1. Rule 26(a)(1) Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) on or before **August 11, 2021**.
2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **June 4, 2022**.
3. Discovery.
 - a. Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **October 14, 2022**.

b. Document production. Document production shall be substantially complete by **July 29, 2022.**

c. Requests for Admission. A maximum of 30 requests for admission are permitted for each side.

d. Interrogatories. A maximum of 25 interrogatories, including contention interrogatories, are permitted for each side.

e. Depositions.

i. Limitation on Hours for Deposition Discovery of Fact Witnesses.
Each side is limited to a total of 70 hours of taking testimony by deposition upon oral examination.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court or by agreement of the parties. A defendant who becomes a cross-claimant or third-party plaintiff shall be considered as having filed an action in this Court for the purposes of this provision.

f. Discovery Matters and Disputes Relating to Protective Orders. Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than seven business days prior to the conference/argument, any party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than five business days prior to the conference/argument,

any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga_civil@ded.uscourts.gov.

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

g. Miscellaneous Discovery Matters.

i. Unless otherwise agreed to by the parties, the parties agree to follow the Court's Default Standard for Discovery.

ii. The parties agree to modify the Default Standard such that: Paragraph 3 disclosures will be due on **August 11, 2021**; Paragraph 4(a) obligations will be due on **August 11, 2021**; Paragraph 4(b) obligations will be due on **September 3, 2021**; Paragraph 4(c) obligations will be due on **October 8, 2021**; and Paragraph 4(d) obligations will be due on **November 12, 2021**.

iii. Other Litigation.

1. United States Patent Nos. 7,417,070 ("the '070 patent"), 7,544,713 ("the '713 patent"), 8,252,839 ("the '839 patent"), 8,349,892 ("the '892 patent"), 8,410,169 ("the '169 patent"), 8,747,897 ("the '897 patent"), 9,050,311 ("the '311 patent"), 9,278,901 ("the '901 patent"), 9,393,203 ("the '203 patent"), and 9,422,223 ("the '223 patent")

were previously asserted against Actavis in connection with Actavis's ANDA seeking approval to market a generic version of Orenitram. *See, e.g., United Therapeutics Corporation v. Actavis Laboratories FL, Inc.*, No. 3-16-cv-03642 (D.N.J.) (filed Jun. 17, 2016); *United Therapeutics Corporation et al v. Actavis Laboratories FL, Inc.*, No. 3-16-cv-01816 (D.N.J.) (filed Mar. 31, 2016). The cases were dismissed pursuant to a stipulation on February 21, 2018. United States Patent Nos. 9,593,066 ("the '066 patent") and 9,604,901 ("the '4901 patent") are asserted in *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, No. 1-20-cv-00755 (D. Del.) (filed Jun. 04, 2020). This litigation remains pending. Liquidia filed a petition for *inter partes* review of the '901 patent in *Liquidia Technologies, Inc. v. United Therapeutics Corporation*, No. IPR2020-00769 (PTAB) (filed Mar. 30, 2020). This IPR remains pending. Liquidia filed a petition for *inter partes* review of the '066 patent in *Liquidia Technologies, Inc. v. United Therapeutics Corporation*, No. PTAB-IPR2020-00769 (PTAB) (filed Mar. 30, 2020). The PTAB denied institution on October 13, 2020.

2. Plaintiff will consider filing further litigation depending on future events, including should a generic manufacturer provide a notice letter stating an intent to seek approval to market a generic version of a product for which Plaintiff has patent(s) listed in the Orange Book.

3. Defendant is still considering whether to file any IPRs. The statutory deadline for filing an IPR is April 5, 2022.

iv. Narrowing of the Asserted Claims and Prior Art References. The parties shall meet and confer regarding asserted claims and prior art narrowing, including limits on the number of Plaintiff's asserted claims and Defendant's asserted prior art references or combinations and any other relevant issue. The parties shall raise any unresolved issues with the

Court pursuant to the provisions of Paragraph 3(f), above, so as to be resolved sufficiently ahead of each deadline set forth below.

v. Within twenty-one days of the Court's Order on claim construction, or if no claim construction is requested, on **September 9, 2022**, Plaintiff shall serve an election of asserted claims, not to exceed a limit agreed upon by the parties or ordered by the Court.

4. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court on or before August 18, 2021. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 3(f), above.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

5. Papers Filed Under Seal. When filing papers under seal, counsel shall deliver to the Clerk the required number of copies as directed in paragraph 6. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

6. Courtesy Copies. The parties shall provide to the Court two courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e.,

appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.

7. Claim Construction Issue Identification. On or before **December 17, 2021**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction; on or before **January 7, 2022** the parties shall exchange their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than **January 21, 2022**. The Joint Claim Construction Chart, in Word format shall be e-mailed simultaneously with filing to rga_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

8. Claim Construction Briefing.¹ Plaintiff shall serve, but not file, its opening brief, not to exceed 5,000 words, on **February 11, 2022**. Defendant shall serve, but not file, its answering brief, not to exceed 7,500 words, on **March 11, 2022**. Plaintiff shall serve, but not

¹ As each brief is written and provided to the opposing party, the individual responsible for verifying the word count will represent to the other party that it has so verified and by what means. These verifications should not be provided to the Court unless a dispute arises about them. Pictures, Figures copied from the patent, and other illustrations do not count against the word limit. Plaintiff should include with its opening brief one or more representative claims with the disputed terms italicized. Should Defendant want to add additional representative claims, Defendant may do so. The representative claims and the agreed-upon claim constructions do not count against the word limits.

file, its reply brief, not to exceed 5,000 words, on **April 1, 2022**. Defendant shall serve, but not file its sur-reply brief, not to exceed 2,500 words, on **April 15, 2022**. No later than **April 22, 2022**, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

I. Representative Claims

II. Agreed-upon Constructions

III. Disputed Constructions

A. [TERM 1]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

B. [TERM 2]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

Etc. The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an appendix, the parties shall submit them in a Joint Appendix.

9. Hearing on Claim Construction. Beginning at **9:00 a.m. on May 26, 2022**, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which answering claim construction briefs are due), the parties shall not present testimony at the argument, and the argument shall not exceed a total of three hours. When the Joint Claim Construction Brief is filed, the parties shall simultaneously file a motion requesting the above scheduled claim construction hearing, state that the briefing is complete, and state how much total time the parties are requesting that the Court should allow for the argument.

10. Disclosure of Expert Testimony.

a. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before **November 11, 2022**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **December 23, 2022**. Reply expert reports from the party with the initial burden of proof are due on or before **February 2, 2023**. No other expert reports will be permitted without either the consent of all parties or leave of the Court. If any party believes that an expert report does not comply with the rules relating to timely disclosure or exceeds the scope of what is permitted in that expert report, the complaining party must notify the offending party within one week of the submission of the expert report. The parties are expected to promptly try to resolve any such disputes, and, when they cannot reasonably be resolved, use the Court's Discovery Dispute Procedure or the complaint will be waived.

Along with the submissions of the expert reports, the parties shall advise of the dates and

times of their experts' availability for deposition. Depositions of experts shall be completed on or before **March 3, 2023**.

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court.

11. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7 .1.1.

12. Pretrial Conference. On **April 28, 2023**, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at **9:00 a.m.** . The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on the fourth business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

13. Motions in Limine. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one filing separate from the motion *in limine*. Each party shall be limited to three *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine*

request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three page submission (and, if the moving party, a single one page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

14. Trial. This matter is scheduled for a three-day bench trial with trial days from 8:30 to 5:00, commencing on **May 8, 2023**. The trial will be timed, as counsel will be allocated a total of ten and one half (10½) hours in which to present their respective cases.

15. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

16. Electronic Service. Pursuant to Federal Rule of Civil Procedure 5(b)(2)(E), the parties agree to accept service by electronic means.

/s/ Richard G. Andrews
UNITED STATES DISTRICT JUDGE